

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>

Questions on SPL:

ER/DL regulatory questions? Send to edrls@fda.hhs.gov

SPL technical questions? Send to spl@fda.hhs.gov

UNII or SRS questions? Send to fda-srs@fda.hhs.gov

As of Feb 23, 2011: DailyMed has over 21,000 SPL loaded.

Minutes:

Combination of SPL IG and Validation Rules - comments/feedback

- Keep at least 2 levels of detail – one for somebody with less technical ability (similar to the IG or Xforms documents)
- What is the plan for the combination – would it work if it were 2 different sections of the same document? Seemed to be some agreement that it would.
- Can't lose the business process part of the document.
- Implementation guide is used by some as a training guide
- Validation rules – some use only after exhausting the implementation guide. Need validation docs when you don't understand the error message(s)

Pharm class indexing file - comments/feedback

- UNII based on active moiety, not active ingredient
- Not linked directly to the product
- FDA has sent files over for NLM testing

Small companies (sponsors) that do SPL

ACTION: Any details you'd like to share on what types of information sources have been most helpful to you, please send along to theresa.m.brunone@gsk.com

Today's anecdote: e-books, training sessions provided by FDA, and SPL Working Group teleconferences have all been particularly useful.

Discontinuation of use of Translation Element for Units of Measure for Strength

Discontinuation of translation data element for units of measure for strength
This element tells what the unit is for the quantity

XML example from Howard showing the difference in the XML:

Here's the before and after snippet showing of the translation element:

Now

```
<asContent>
  <quantity>
    <numerator value="120" unit="1">
      <translation code="C48542"
codeSystem="2.16.840.1.113883.3.26.1.1" displayName="TABLET"/>
    </numerator>
    <denominator value="1"/>
  </quantity>
```

After removing <translation>:

```
<asContent>
  <quantity>
    <numerator value="120" unit="1">
    </numerator>
    <denominator value="1"/>
  </quantity>
```

We strongly encourage those who code (vendors, people coding using basic XML tools) to attend Technical Team meeting for more information.

Tech Team meeting is Monday, Feb 28. 2-3PM (EST).

Dial-in information: 770-657-9270 Participation code: 745896#

NLM Mobile App for SPL

If you have a mobile phone, you can now view SPL from the DailyMed site.

FDA On-Line Repository

Check it out here: <http://labels.fda.gov>

Device Team: New version of Xforms being tested

Devices minutes from Feb 10

[http://wiki.hl7.org/images/1/1d/Medical Product Information minutes Feb 10 2011.doc](http://wiki.hl7.org/images/1/1d/Medical_Product_Information_minutes_Feb_10_2011.doc)

Devices meeting with demo of new version: Feb 24, 2011

To get the XFORMS tool:

(1) You will need to register at the Pragmatic Data website.

(2) Then go to this address:

<http://pragmaticdata.com/spl/form/>

The tool is offered as a web-based editor. You can load and save files to your local drive using the software that is located on the Pragmatic server. The web-based editor will always be the latest version of the tool. It can be used with Internet Explorer 6.0 and up, Google Chrome, Firefox, and Safari.

The tool includes templates for device and drug submissions (Home Use Medical devices, UDI submission, Labeler Code Request, Establishment Registration, Drug listing, Substance Indexing).

Updates from ER/DL, OTC teams

Several special sessions in planning:

- educational session with representative from FirstDataBank on how NDC data is used, how it interacts with reimbursement and billing concerns
- educational session with CMS representative(s) on how eList data (particularly NDC codes) is used by CMS
- Q&A session with DRLS group (FDA) and possibly representatives also from CBER, CVM, and OC - Imports

Next meeting scheduled for:

Wednesday, Mar 10, 2011

Time: 1:00-2:30 ET

Dial-in info: number 1-877-423-2663 PIN# 240184

- Minutes of previous Process Team meetings are here:
<http://spl-work-group.wikispaces.com/Process+Communications+Forum>